LETTER TO THE EDITOR

Intermittent use of inhaled corticosteroids for the treatment of mild asthma is not recommended

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Dear Sir,

We read with interest the short report by Hyland *et al.* published recently in this journal.¹ We are very concerned that, both in the introduction and discussion, there is an implication that intermittent use of inhaled steroids for mild asthma is safe and that somehow guidelines have ignored this.

The Pharmacological Management Evidence Review Group of the British Guideline on the Management of Asthma has looked carefully at this issue. In patients with mild asthma, regular use of inhaled corticosteroids improves symptoms, has a small effect in improving lung function, reduces the requirement for rescue β_2 -agonist use and, most importantly, reduces the exacerbation rate. The study by Papi *et al.* used high dose inhaled steroid (beclometasone dipropionate 250mcg per puff) in a combination inhaler with salbutamol.² There were just over 100 patients in each group and this study was underpowered to show any difference in exacerbations requiring oral steroids. The study by Boushey *et al.* was also underpowered with only 70 patients per group; indeed, the authors describe it in their discussion as a preliminary study.³ Although the primary outcome measure of morning peak expiratory flow showed no difference between the groups, those treated with regular budesonide, 200mcg per day, had more symptom-free days, lower sputum eosinophil level, lower exhaled nitric oxide values, greater improvement in bronchial hyper-responsiveness, and a greater improvement in asthma control score. Furthermore, the blinded part of the trial was preceded by pre-treatment with either budesonide 800mcg twice daily for ten days or prednisone 0.5mg per kilogram for five days.

Most importantly, three larger and longer studies have shown that regular inhaled steroids are beneficial in mild asthma. The START study investigated 5000 patients over a three-year period and showed a marked reduction in exacerbation rate with a small improvement in lung function.⁴ The OPTIMA study again showed that regular use of inhaled steroids led to improvement in lung function and reduced exacerbation rate.⁵ Finally, a recently published study by Reddel *et al.* also showed the beneficial effect of regular low dose inhaled steroids.⁶

In conclusion, we think that the evidence for regular use of inhaled corticosteroids in mild asthma – as opposed to ‘as required’ use – is overwhelming. It would require much larger and longer term studies than the ones quoted to overturn current guideline recommendations. The variation in practice between respiratory nurses reported in the paper by Hyland *et al.*¹ is likely to lead to poorer asthma control and increased risk of exacerbations.

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Authors' reply

We thank Prof Barnes, Dr Douglas and Dr Higgins for their comments on our recent paper.¹

There can be little doubt that the surest way to prevent exacerbations in asthma is for the patient to take regular inhaled steroids – and of sufficient enough dose – to prevent the breakthrough of inflammation on the background of an inflammatory pathophysiology which is intrinsically variable. The problem is that just under 50% of patients (the exact figure varies with methodology and population²) do not wish to take regular inhaled steroids. Of these patients, some have had exacerbations in the past, some have not; and of those who have not, some will go on to have exacerbations and some will not. The question is: how does one manage these non-compliant patients, particularly in light of the fact that they are a heterogenous group?

There are two conflicting views about the way to manage non-compliance. The compliance model is based on the argument that asthma is a potentially fatal disease, that the safest strategy is regular inhaled steroids, and that all patients ought to comply because doing so is in their best interest. The clinician therefore needs to keep educating patients until they comply. The concordance model is based on the assumption that optimum management is achieved by compromise and shared decision-making.³ Those supporting the concordance view point out that the compliance model can be ineffective – i.e. despite education many patients do not comply and can resent didactic instruction. Additionally, different forms of non-compliance are not equally unsafe. For example, survey data suggest that the 'constant but less' strategy is less effective than 'symptom-based use' of inhaled steroids.⁴ By finding common ground and engaging with the patient, the clinician is in a better position to advise against unsafe practice. The empirical evidence for either model (i.e. compliance versus compromise with guidelines) is limited.

The variation in the behaviour of the respiratory nurses noted in our paper¹ may reflect variation in views on compliance versus concordance. Many of the nurses were using targeted advice for symptomatic use of inhaled steroids, though the basis for selecting patients for that advice is unknown. None of the clinical trials cited either by us, or by Barnes, Douglas and Higgins above, included a treatment arm where symptomatic use was targeted to particular patients – so these studies have little bearing on the management strategy of nurses in our study. More importantly,

clinical trials of drug regimens are conducted on patients who are willing to take part and who (in some cases) are deemed compliant by their doctor. Patients who deny they have asthma and are non-compliant are often excluded from such trials, yet it is precisely these patients that can pose problems for patient management and for whom compromise may be needed.

The purpose of guidelines is not just to be a repository of correct information, but to achieve consistency of behaviour amongst clinicians. The nurses in our study were not only deviating from those guidelines but there was also considerable variation in practice between nurses. Two logical points derive from this observation. First, the guidelines are not achieving their objective in producing consistent behaviour amongst clinicians. Second, not all the nurses can be giving optimum advice – although some *may* be. We cannot say from our survey data which nurses are achieving better outcomes than others because an ethics committee requirement was that individual nurses could not be identified. Nor do our data show whether the concordance model, if it were being applied, was producing a better or worse outcome. However, it seems evident from the above that the guidelines do not provide adequate guidance about managing non-compliance – i.e., about half the patients in clinical practice. This inadequacy reflects lack of current knowledge which urgently needs to be addressed.

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